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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,097	07/06/2005	Maria Elena de Lima Perez-Garcia	B1204/20002	5628

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EXAMINER	
HAMIDINIA, SHAWN A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,097	PEREZ-GARCIA ET AL.	
	Examiner	Art Unit	
	Shawn Hamidinia	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *2 and 4-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1 and 3) in the reply filed on March 24, 2006 is acknowledged. The traversal is on the grounds that the claims of Group I-VII are directed to the same inventive concept in that the claimed invention comprises the same special technical feature of a purified albumin solution of human origin. This is not found persuasive because claim 3 reads on a single amino acid. Since amino acids are known, claim 3 does not define a contribution over the prior art and therefore the groups lack a common special technical feature. Furthermore, since searching the independent and distinct inventions of Group II-VII would impose a serious search burden. Thus, the requirement is still deemed proper and is therefore made FINAL. Claims 2 and 4-9, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim.

2. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Priority

3. The current application filed on July 6, 2005 is a 371 application of PCT/BR03/00073 filed on June 9, 2003, which claims benefit of Brazilian application 0202157-9 filed on June 7, 2002.

Information Disclosure Statement

4. No information disclosure statements have been received.

Claim Rejections - 35 USC § 112, Second Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the applicant does not use the phrase, "wherein the peptide is an anti-hypertensive agent". It is completely unclear as to what the applicant is claiming to be the invention without this phrase included in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112-Enablement

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for "partial" or "modified" polypeptides of SEQ ID NO: 1-4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to

make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404).

Factors to be considered in determining whether a disclosure would require undue experimentation include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, (1) the amount of experimentation is large because of the diverse variety of polypeptides that are encompassed within a partial or modified sequence of SEQ ID NO: 1, 2, 3, or 4, sequences that are over 23 residues in length. Hence, a polypeptide that has 12 residues allows for over 50% of the polypeptide to vary which would be at least 13 residues. The number of changes this allows is astronomical (all 13 positions could be modified by 19 other amino acids alone or in any combination). (2) Also, there is no guidance provided by the specification on how to use the polypeptide of SEQ ID NO: 1-4 or related polypeptides. The specification does not describe how the polypeptide sequence of SEQ ID NO: 1-4 will be used and whether it will remain an anti-hypertensive agent. Further, (3) the specification is totally devoid of any working examples other than an isolated sequence listing for SEQ ID NO: 1-4; As for the next Wands factor, (4) the nature of the invention is an isolated or synthetic peptide comprising a complete, partial or modified sequences of SEQ ID NO: 1-4.

There is no prior art (5) to the complete polypeptides of SEQ ID NO: 1-4; (6) the relative level of skill in this art is very high; (7) the predictability of the art is low with regard to the determination of the function of any of these partial or modified polypeptides as anti-hypertensive agents. Finally, (8) the claims are extremely broad because a single amino acid is encompassed by a partial sequence of SEQ ID NO: 1-4, which is completely undefined and uncharacterized.

Based on this analysis, the conclusion that it would require undue experimentation to practice the instant invention is inescapable.

Claim Rejections - 35 USC § 112, First Paragraph-Written Description

9. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated or synthetic peptide comprising a complete, partial or modified sequences of SEQ ID NO: 1-4.

The claimed invention does not meet the current written description requirements for the following reasons. Firstly, substantial variation in structures and functions are expected among polypeptides that are partial sequences of SEQ ID NO: 1-4, polypeptide sequences that range from 24 to 25 amino acids in length. Therefore, the disclosure of SEQ ID NO: 1-4 does not provide adequate written description for all

partial or modified polypeptides of SEQ ID NO: 1-4. Since Applicant does not have any representative examples of a single species of a partial or modified polypeptide of claim 3, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms. Given this lack of disclosure, Applicants' written description of the claimed invention is insufficient to show that Applicants were in possession of the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by a single amino acid.

The claim is directed to an isolated or synthetic peptide comprising a complete, partial or modified sequences of SEQ ID NO: 1-4. Since amino acids are known in the art, a "partial" sequence of SEQ ID NO: 1-4 is anticipated.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawn Hamidinia whose telephone number is (571) 272-4534. The examiner can normally be reached on Mon-Fri from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SAH

ROBERT A. WAX
PRIMARY EXAMINER